



## TEXAS DEPARTMENT OF INSURANCE

### Division of Workers' Compensation - Medical Fee Dispute Resolution (MS-48)

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## MEDICAL FEE DISPUTE RESOLUTION FINDINGS AND DECISION

### GENERAL INFORMATION

**Requestor Name**

American Specialty Pharmacy

**Respondent Name**

General Motors LLC

**MFDR Tracking Number**

M4-15-3897-01

**Carrier's Austin Representative**

Box Number 47

**MFDR Date Received**

August 3, 2015

### REQUESTOR'S POSITION SUMMARY

**Requestor's Position Summary:** "Trepadone is **medically necessary:** ... to decrease pain ... to decrease inflammation ... to allow activities of daily living ... to allow the patient to work ...

Nalfon 400mg is **medically necessary:** ... to decrease pain ... to decrease inflammation ... to allow activities of daily living ... to allow the patient to work ...

Trezix is **medically necessary:** ... to decrease pain ... to allow activities of daily living ... to allow the patient to work ..."

**Amount in Dispute:** \$610.10

### RESPONDENT'S POSITION SUMMARY

**Respondent's Position Summary:** "This claim is managed by the Southwest Healthcare Network."

**Response Submitted by:** Downs-Stanford, P.C.

### SUMMARY OF FINDINGS

Dates of Service	Disputed Services	Amount In Dispute	Amount Due
July 1, 2015	Trepadone, Nalfon, and Trezix	\$610.10	\$500.60

### FINDINGS AND DECISION

This medical fee dispute is decided pursuant to Texas Labor Code §413.031 and applicable rules of the Texas Department of Insurance, Division of Workers' Compensation.

**Background**

1. 28 Texas Administrative Code §133.305 defines the terms used for medical disputes.
2. 28 Texas Administrative Code §133.307 sets out the procedures for resolving medical fee disputes.
3. 28 Texas Administrative Code §134.1 sets out the general medical reimbursement guidelines for non-network care.

4. 28 Texas Administrative Code §134.500 defines specific terms associated with pharmaceutical services.
5. 28 Texas Administrative Code §134.503 sets out the fee guidelines for pharmaceutical services.
6. Texas Insurance Code §1305.101 defines the duties of networks to provide medical treatment.
7. The insurance carrier reduced payment for the disputed services with the following claim adjustment codes:
  - B5 – Payment adjusted because coverage/program guidelines were not met or were exceeded.
  - OA – The amount adjusted is due to bundling or unbundling of services.

### Issues

1. Are medical foods addressed in the division's pharmacy fee guidelines?
2. Did the requestor receive an out-of-network referral from the injured employee's treating doctor that has been approved by the network pursuant to §1305.103?
3. Is this dispute eligible for medical fee dispute resolution pursuant to 28 Texas Administrative Code §133.307?
4. Is the insurance carrier's reason for denial of payment for Nalfon and Trexiz supported?
5. What is the total reimbursement for the disputed service?
6. Is the requestor entitled to additional reimbursement?

### Findings

1. In resolving disputes over the amount of payment due for services determined to be medically necessary and appropriate for treatment of a compensable injury, the role of the division's medical fee dispute resolution program is to adjudicate the payment given the relevant statutory provisions and rules. 28 Texas Administrative Code §134.1 titled *Medical Reimbursement* states in pertinent part that

(e) Medical reimbursement for health care not provided through a workers' compensation health care network shall be made in accordance with:

- (1) the Division's fee guidelines;
- (2) a negotiated contract; or
- (3) in the absence of an applicable fee guideline or a negotiated contract, a fair and reasonable reimbursement amount as specified in subsection (f) of this section.

Provision at Rule §134.1(e)(1) is first considered. The requestor billed the service in dispute using a DWC Form-066 Statement of Pharmacy Services. The rules and regulations for pharmacy services are found at Texas Administrative Code Title 28, Part 2, Chapter 134, Subchapter F, including fee guidelines for pharmacy services are found at §134.503. According to the medical bill, the disputed service includes Trepadone. Available information about Trepadone indicates that it is a medical food. For example, Trepadone is found in the Official Disability Guidelines under the procedure/topic "Medical Food."

To determine whether a fee guideline for medical foods is found in Subchapter F, the division examines the applicability portions of 28 Texas Administrative Code §134.503 amended to be effective October 23, 2011 (36 TexReg 6949), along with relevant definitions of terms pursuant to 28 Texas Administrative Code §134.500, adopted to be effective January 17, 2011 (35 TexReg 11344). Rule §134.503 states, in pertinent part:

- (a) Applicability of this section is as follows: (1) This section applies to the reimbursement of **prescription drugs** and **nonprescription drugs or over-the-counter medications** as those terms are defined in §134.500 of this title (relating to Definitions) for outpatient use in the Texas workers' compensation system

The definition of those terms under Rule §134.500 are as follows:

- (8) Nonprescription drug or over-the-counter medication--A non-narcotic **drug** [emphasis added] that may be sold without a prescription and that is labeled and packaged in compliance with state or federal law...
- (12) Prescription **drug** [emphasis added] -- (A) A substance for which federal or state law requires a prescription before the substance may be legally dispensed to the public; (B) A **drug** [emphasis added] that under **federal law** [emphasis added] is required, before being

dispensed or delivered, to be labeled with the statement: "Caution: federal law prohibits dispensing without prescription;" "Rx only;" or another legend that complies with federal law; or (C) A **drug** [emphasis added] that is required by federal or state statute or regulation to be dispensed on prescription or that is restricted to use by a prescribing doctor only.

That is, only substances considered prescription drugs, nonprescription drugs, or over-the-counter drugs by federal law are addressed in the fee guideline Rule §134.503. Additionally, the definition of closed formulary at Rule §134.500(3) clarifies that substances approved by the Food and Drug Administration (FDA) as prescription and nonprescription drugs form the basis for the pharmacy closed formulary. The FDA is therefore the federal program that the division relies upon in order determine whether a medical food, such as Trepadone, is categorized as a prescription drug, nonprescription drug, or an over-the-counter drug for the purposes of the formulary and application of fees pursuant to Rule §134.503.

Information found on the FDA website indicates that Medical foods are **not** regulated as drugs. Under the FDA's [Compliance Program Guidance Manual \(CPGM\)](#), medical foods are categorized under and regulated as "Food and Cosmetics." Specifically, under the Food Compliance Program numbered 7321.002 titled *Medical Foods – Import and Domestic*, implemented on August 24, 2006, the FDA states that "Only food regulations apply to medical foods." The division therefore concludes that the Trepadone, a medical food and one of the services in dispute, is not addressed in Texas Administrative Code Title 28, Part 2, Chapter 134, Subchapter F because it is not regulated as a drug by the FDA. Consequently, a fee for the service in dispute cannot be established pursuant to 28 Texas Administrative Code §134.503.

Furthermore, review of the available documentation finds no service codes or assertions made by the requestor which point to other fee guidelines established under Texas Administrative Code Title 28, Part 2, under Chapter 134, nor does the division find evidence of a negotiated contract for the service in dispute. Pursuant to 28 Texas Administrative Code §134.1(e), the division therefore concludes that §134.1(e)(3) applies to the services in dispute.

2. The requestor filed this medical fee dispute to the Division asking for resolution pursuant to 28 Texas Administrative Code §133.307. The authority of the Division of Workers' Compensation is to apply Texas Labor Code statutes and rules, including 28 TAC §133.307, is limited to the conditions outlined in the applicable portions of the Texas Insurance Code, Chapter 1305. Texas Insurance Code §1305.101(c) states, **Notwithstanding any other provision of this chapter, prescription medication or services, as defined by Section 401.011(19)(E) [emphasis added], Labor Code, may not, directly or through a contract, be delivered through a workers' compensation health care network [emphasis added].** Prescription medication and services shall be reimbursed as provided by Section 408.0281, Labor Code, other provisions of the Texas Workers' Compensation Act, and applicable rules of the commissioner of workers' compensation.

Because Trepadone does not meet the definition of a drug subject to the division pharmacy exclusion in Texas Insurance Code §1305.101(c), the disputed services are subject to TIC §1305.153(c) which provides that "Out-of-network providers who provide care as described by Section 1305.006 shall be reimbursed as provided by the Texas Workers' Compensation Act and applicable rules of the commissioner of workers' compensation."

Texas Insurance Code §1305.006(3) states, "health care provided by an out-of-network provider pursuant to a referral from the injured employee's treating doctor that has been approved by the network pursuant to Section 1305.103."

The requestor therefore has the burden to prove that the condition(s) outlined in the Texas Insurance Code §1305.006 were met in order to be eligible for dispute resolution. Texas Insurance Code §1305.103 requires that:

- (e) A treating doctor shall provide health care to the employee for the employee's compensable injury and shall make referrals to other network providers, or request referrals to out-of-network providers if medically necessary services are not available within the network. Referrals to out-of-network providers must be approved by the network. The network shall approve a referral to an out-of-network provider not later than the seventh day after the date on which the referral is

requested, or sooner if circumstances and the condition of the employee require expedited approval. If the network denies the referral request, the employee may appeal the decision through the network's complaint process under Subchapter I.

The requestor has the burden to prove that it obtained the appropriate approved out-of-network referral for the out-of-network healthcare it provided. Review of the submitted documentation does not find a referral was from the treating doctor and approved by the network to treat the injured employee. The Division concludes that the requestor has therefore failed to meet the requirements of Texas Insurance Code §1305.103.

3. The Division finds that the requestor failed to prove in this case that the requirements of Texas Insurance Code §1305.006(3) were met for the dispensation of Trepadone. Consequently, this disputed service is not eligible for medical fee dispute resolution pursuant to 28 Texas Administrative Code §133.307.

Information found on the FDA website indicates that Nalfon and Trezix are regulated as drugs. The Preamble of 28 Texas Administrative Code §134.540, effective January 17, 2011, 35 TexReg 11344, states that the rule "concerns the requirements for the use of the pharmacy closed formulary for claims subject to certified networks." In addition, "the Division notes the closed formulary applies to both certified network and non-network claims, and may not be amended by system participants."

While the claim is part of a certified network, the treatments, Nalfon and Trezix included in this dispute, may not be delivered through a health care network and are subject to the fee guidelines found in 28 Texas Administrative Code §134.503 and the closed formula guidelines found in 28 Texas Administrative Code §134.540. Further, because prescription medications may not be delivered through a workers' compensation health care network, the fee dispute for Nalfon and Trezix is subject to dispute resolution in accordance with 28 Texas Administrative Code §133.307.

4. The insurance carrier denied payment for Nalfon and Trezix, in part, using claim adjustment code OA – "The amount adjusted is due to bundling or unbundling of services." Review of the relevant fee guidelines finds that these services are not subject to bundling rules.
5. The total reimbursement for the disputed services is established by the AWP formula pursuant to 28 Texas Administrative Code §134.503(c), which states, in relevant part:

- (c) The insurance carrier shall reimburse the health care provider or pharmacy processing agent for prescription drugs the lesser of:
- (1) the fee established by the following formulas based on the average wholesale price (AWP) as reported by a nationally recognized pharmaceutical price guide or other publication of pharmaceutical pricing data in effect on the day the prescription drug is dispensed:
- (A) ...
- (B) Brand name drugs:  $((\text{AWP per unit}) \times (\text{number of units}) \times 1.09) + \$4.00$  dispensing fee per prescription = reimbursement amount...
- (2) notwithstanding §133.20(e)(1) of this title (relating to Medical Bill Submission by Health Care Provider), the amount billed to the insurance carrier by the:
- (A) health care provider

The requestor is seeking reimbursement for brand name drugs Nalfon, NDC 42195030809 and Trezix, NDC 66992084010. The disputed medication was dispensed on July 1, 2015. The reimbursement is calculated as follows:

Date of Service	Prescription Drug	Calculation per §134.503 (c)(1)	§134.503 (c)(2)	Lesser of §134.503 (c)(1) & (2)	Carrier Paid	Balance Due
7/1/15	Nalfon	$(4.10822 \times 90 \times 1.09) + \$4.00 = \$407.02$	\$299.10	\$299.10	\$0.00	\$299.10
7/1/15	Trezix	$(3.35970 \times 60 \times 1.09) + \$4.00 = \$223.72$	\$201.50	\$201.50	\$0.00	\$201.50

6. The total reimbursement amount for the disputed service is \$500.60. The insurance carrier paid \$0.00. An additional reimbursement of \$500.60 is recommended.

### **Conclusion**

For the reasons stated above, the Division finds that the requestor has not established that additional reimbursement is due. As a result, the amount ordered is \$500.60.

### ***ORDER***

Based upon the documentation submitted by the parties and in accordance with the provisions of Texas Labor Code Sections 413.031 and 413.019 (if applicable), the Division has determined that the requestor is entitled to additional reimbursement for the services involved in this dispute. The Division hereby ORDERS the respondent to remit to the requestor the amount of \$500.60 plus applicable accrued interest per 28 Texas Administrative Code §134.130, due within 30 days of receipt of this Order.

### **Authorized Signature**

_____	Laurie Garnes	February 18, 2016
Signature	Medical Fee Dispute Resolution Officer	Date

### ***YOUR RIGHT TO APPEAL***

Either party to this medical fee dispute has a right to seek review of this decision in accordance with 28 Texas Administrative Code §133.307, 37 *Texas Register* 3833, applicable to disputes filed on or after June 1, 2012.

A party seeking review must submit a **Request to Schedule a Benefit Review Conference to Appeal a Medical Fee Dispute Decision** (form **DWC045M**) in accordance with the instructions on the form. The request must be received by the Division within **twenty** days of your receipt of this decision. The request may be faxed, mailed or personally delivered to the Division using the contact information listed on the form or to the field office handling the claim.

The party seeking review of the MFDR decision shall deliver a copy of the request to all other parties involved in the dispute at the same time the request is filed with the Division. **Please include a copy of the *Medical Fee Dispute Resolution Findings and Decision*** together with any other required information specified in 28 Texas Administrative Code §141.1(d).

**Si prefiere hablar con una persona en español acerca de ésta correspondencia, favor de llamar a 512-804-4812.**